U.S. Environmental Protection Agency
Office of Research and Development

BOARD OF SCIENTIFIC COUNSELORS
HUMAN HEALTH SUBCOMMITTEE

Conference Call Summary
February 24, 2005
12:00 noon–2:00 p.m. EST

Welcome
Dr. James Klaunig, Chair, Human Health Subcommittee

Dr. Klaunig welcomed the participants to the conference call. After a roll call, he answered a question from Dr. Joseph Landolph about the amount of material that lead writers should have ready in advance of the face-to-face meeting on February 28. The subcommittee members should read the background materials, the lead writers should compose a draft before the meeting, and the contributors should be prepared to submit their comments electronically to the lead writer on the morning of February 28. The lead writers then can incorporate those comments into their drafts. A synopsis of the findings will be presented on the last day of the meeting, and at least one more conference call will be scheduled to finalize the document.

Orientation to EPA
Dr. Larry Reiter, Executive Lead for the Human Health Research Program, EPA

Dr. Reiter provided background information for the program review by describing the structure of the Office of Research and Development (ORD), the strategic planning process at EPA, EPA's core and problem-driven research, and the multi-year planning (MYP) process.

EPA's organizational structure is based on three major components: the Program Offices, ORD, and the Regions. The responsibility for the regulatory agenda falls to the various Program Offices (water, air, pesticides, etc.). The Regions are responsible for the implementation and execution of the statutes and serve as the interface with the states. ORD has primary responsibility for developing and delivering the science to the Program Offices and Regions. The planning process is very participatory. In 1995, ORD reorganized and created three national laboratories (National Exposure Research Laboratory, National Health and Environmental Effects Research Laboratory, and National Risk Management Research Laboratory) and two national centers (National Center for Environmental Assessment and National Center for Environmental Research). The National Center for Homeland Security and the National Center for Computational Toxicology were created more recently.

After giving a "biosketch" of ORD, Dr. Reiter described its mission—to advance scientific knowledge to solve the environmental problems that the Agency faces. He mentioned the three major components of the mission: (1) the conduct of research, (2) support through advice and

assistance to Program Offices and Regions, and (3) the provision of scientific leadership to the Agency and the broader scientific community. Dr. Reiter presented a summary of the levels of strategic planning that are carried out within EPA. Five strategic goals are linked to statutes: (1) clean air and global climate, (2) clean and safe water, (3) land preservation and restoration, (4) healthy communities and ecosystems, and (5) compliance and environmental stewardship.

ORD developed a strategic plan that articulates the high-priority research areas captured in the Agency's strategic plan. ORD's research strategies attempt to define the critical scientific questions that must be addressed in a research program. Its MYPs develop long-term goals (LTGs) and a roadmap to achieve the LTGs through a program of research. The MYPs are influenced by a number of factors, including EPA's annual performance plans, guidance from the Administration, and the ORD annual planning process. The laboratories develop implementation plans that flesh out a research agenda with priorities and define critical paths for the way in which the research will address the LTGs. The Divisions then generate research plans that are consistent with the overall planning process and deliver research products and outputs that address the overall Agency needs. All of the steps of the process include input from multiple stakeholders and external peer review.

Describing the relationship between core and problem-driven research, Dr. Reiter stated that EPA invests about 60 percent of its resources in problem-driven research and 40 percent of its resources in core research. Human health research is one of the core areas, with application to a number of problem-driven research areas, such as particulate matter, air toxics, safe pesticides and safe products, drinking water, computational toxicology, and endocrine disruptors.

The MYPs serve as a tool to address EPA's high-priority science questions, provide information to assist and support resource decisions, demonstrate how programs contribute to EPA's strategic goals, assist in determining the accountability of performance, provide information for the Program Assessment Rating Tool (PART) review by the Office of Management and Budget (OMB), and communicate research inside and outside the Agency. The 15 MYPs developed in ORD can be categorized as either problem-driven research or core research. The resources devoted to the various programs vary considerably.

To summarize his presentation, Dr. Reiter stated that ORD's research is organized across the risk assessment paradigm (the exposure-to-dose-to-effect continuum). Strategic planning identifies key research needs related to the Agency's mission with a balance of core and problem-driven research. Core research provides fundamental research in support of problem-driven areas. Multi-year planning determines the Laboratory/Center approach to address the needs over a 5- to 10-year period.

Dr. James Clark posed a question about how often the MYP is updated. Dr. Reiter replied that each plan has undergone about three revisions, usually on a 3-year cycle.

In response to a question from Dr. Landolph about the decision-making process, Dr. Reiter stated that a number of forums are involved, including the ORD Executive Council and research coordination teams. These groups discuss emerging issues and priorities. When major shifts in resources are involved, the decision requires a consideration of the congressional budget. On the

other hand, decisions to shift priorities within research areas are considered during the annual planning process.

Dr. Timothy Buckley asked about the split between problem-driven and core research and coordination with other federal agencies involved in similar research. Dr. Reiter explained that the dialogue involved in generating the research agendas includes discussions with other federal agencies. He offered an example of this interaction in the area of endocrine disruptors by describing the interaction with the White House Office of Science and Technology Policy's Committee on Environment and Natural Resources. Representatives from 14 agencies formed a working group and developed an inventory of research across the federal government in the area of endocrine disruption, developed a list of the key science questions to be addressed in a research program, and determined the gaps in the research. Joint solicitations were issued to support grants in the area of endocrine disruptors. In response to a question about whether the process is formal or informal, Dr. Reiter stated that the interaction occurs in the development of the ORD research strategies and MYP plans. Regarding the 60-40 split between problem-driven and core research, Dr. Reiter explained that the split influences where the research focuses but not the commitment to creating a balanced portfolio.

Dr. Landolph asked about ORD's ability to deal with emerging issues for which it has no expertise. Dr. Reiter explained that ORD works in three ways: (1) the intramural program, (2) the grants program, and (3) laboratory-based extramural work. In the grants program, ORD supports research in targeted areas. In the laboratory work, ORD is able to enlist expertise from academic institutions to address scientific questions.

EPA's Human Health Research Program
Dr. Hugh Tilson, National Program Director for the Human Health Research Program, EPA

Dr. Tilson presented information about the approach behind the program review, gave a brief overview of the Human Health Research Program, and described the program design and the MYP.

The program review is meant to provide guidance to ORD to help assess the progress and direction of the Human Health Research Program; plan, implement, and strengthen the program; and make research investment decisions over the next 5 years. The program review also will address the research and development of federal investment criteria, including the conduct of prospective and retrospective reviews and the examination of relevance, quality, and performance. Feedback also is encouraged on scientific leadership. In addition, output from the subcommittee will help ORD to prepare for its OMB review in April 2005.

After describing the proposed format for the Human Health Research Program review, Dr. Tilson enumerated the four main themes, or long-term goals (LTGs), of the program: (1) harmonization of risk assessment, (2) aggregate/cumulative risk, (3) susceptible subpopulations, and (4) research to evaluate the effectiveness of public health outcomes. The strategic drivers for the research program are legislative and congressional mandates, administrative priorities, agency priorities, Regional and Program Offices, and the scientific community.

The four LTGs call for risk assessors and risk managers to use ORD's methods and models to (1) decrease uncertainty in risk assessment, (2) characterize aggregate/cumulative risk, (3) identify susceptible subpopulations, and (4) develop approaches to evaluate public health outcomes of risk management decisions. Achieving the LTGs will in turn reduce human exposure to environmental stressors. Dr. Tilson listed the key research questions for the LTGs and described the design of the research program. He concluded his presentation with a description of the conceptual framework for the human health research program. An example served to elucidate the relationship between the MYP and the program design and to demonstrate the way in which an LTG guides the program design and the way in which advances in research knowledge lead to achieving an LTG.

Dr. Buckley asked how ORD views a health outcome such as obesity and its relationship to the environment. Dr. Hal Zenick responded that views obesity as a susceptibility modifier. Dr. Buckley asked about the built environment or stress as an exposure of interest. Dr. Reiter mentioned the Institute of Medicine's roundtable on environmental health issues, which is examining the natural, built, and social environments. EPA has no regulatory program dealing with indoor air, but it does provide guidance on issues related to indoor air. Dr. Tilson stated that EPA would be interested in how stress interacts with environmental pollutants. Dr. Zenick posed the question of whether environmental factors for which EPA is responsible could contribute to obesity. The question involves the identification of the environmental factors. Dr. Donald Mattison stated that this topic fits into exposure factors issues, a fundamental characterization of population attributes. A participant questioned the extent to which EPA considers nontraditional environments, such as the built environment or social stressors, which might be important in terms of disease outcome either as susceptibility factors or in a causal link. Another participant pointed out that the Agency's cumulative risk guidance document recognizes the issue of multistressors, but EPA is not well equipped to take on these complicated questions.

Dr. Elaine Symanski asked about the conceptual framework for the Human Health Research Program. The outputs that the program generates are used by EPA's clients. Are there any formal mechanisms that guide non-EPA clients to produce optimal outcomes based on the generated information? The response was that outcomes from the research program enter into the public domain, and a framework exists to assess the information. Dr. Reiter noted that the question raises a major challenge to ORD in terms of communication. Information must be conveyed to the appropriate people in a useable form. After a body of research is completed, EPA is committed to writing synthesis documents that summarize the research in an appropriate perspective. Accomplishment reports also summarize complex issues in an understandable manner. In addition, EPA provides scientists to participate in public forums. For the past 3 years, science forums have been held in Washington, DC, in an attempt to convey the scientific information to the public in an understandable manner.

Administrative Procedures
Virginia Houk, DFO, Human Health Subcommittee

Ms. Houk reviewed information regarding the timesheet, the travel voucher form, and logistics for the face-to-face meeting:

- Subcommittee members should use the timesheets to document their "homework" time for reimbursement. The timesheets will be collected at least two times, once at the face-to-face meeting and again in April.
- Subcommittee members should use the travel voucher form to itemize their travel costs. Receipts should be included. For airline tickets, the itinerary is the electronic ticket.
- EPA will provide transportation between the hotel and the meeting location. Participants should meet at 7:30 a.m. on Monday. Photo IDs are needed.
- A group dinner is planned for Monday night at George's Garage in Durham.
- Participants are encouraged to bring their own laptop computers for use during the working sessions.
- Another conference call will be scheduled as a followup to the meeting to finalize the report, possibly at the end of March or beginning of April.

Additional Needs and Action Items

Dr. Klaunig reported that some additional meeting rooms will be available Tuesday evening and during the meeting if small groups (three or fewer individuals) would like to meet.

Action items from the conference call are as follows:

- Ms. Houk will check on the procedure for payment of airline travel.
- Subcommittee members will inform Ms. Houk if they will not be taking the van from the hotel to the meeting location.
- Subcommittee members with logistics questions can contact Ms. Houk by phone or e-mail. She will send them her home telephone number in case of an emergency.
- Subcommittee members can pick up the poster miniatures at the front desk of the hotel on check-in.

Ms. Houk asked for public comment, and there was none. The conference call ended at 1:52 p.m.

List of Participants

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